Exhibit C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF POLYMER CHEMICAL TECHNOLOGIES, LLC OF

DR. RUSSELL DUNN, M.S., Ph.D., P.E.

I. QUALIFICATIONS

Russell F. Dunn, Ph.D. P.E.

I received my Bachelor's and Master's degree in chemical engineering from Auburn University in 1984 and 1988 respectively and my Ph.D. in chemical engineering from Auburn University in 1994. I wrote my dissertation on the Synthesis of Optimal Heat-Induced and Energy-Induced Separation Networks for Waste Minimization. I have been a Registered Professional Engineer in the State of Florida since 2003.

I am the President and Founder of Polymer Chemical Technologies, LLC, which I formed in 2004. Through this company I have been involved in well over 140 projects focusing on process and product design issues, process and product safety and polymer product analysis. I have also established a polymer analysis lab through this company. I have written in excess of 200 technical reports on polymer failure analysis and product and process design through this company in response to client needs and several of these reports were studies of polypropylene-based products. Many of these technical reports have included an assessment of the safety analysis that was conducted be the manufacture on their product design. Much of the work conducted through Polymer Chemical Technologies to date addresses design issues for large chemical and polymer manufacturing clients.

Prior to founding Polymer Chemical Technologies, I worked as a Chemical Engineering Consultant for McSwain Engineering, Inc. for three years, and prior to that I worked at Solutia, formerly Monsanto Chemical Company from 1995 to 2001. At Monsanto I was a Research Specialist, specializing in Nylon Plastics, Polymer and Industrial Fibers technologies, a Senior Research Specialist and Research Team Leader in Nylon Plastics Technology and, finally, I was a Science Fellow and Research Team Leader. I also worked to Ampex Corporation from 1985-1989 where I was a Manufacturing Manager for three years and a Senior Engineer/Staff Engineer in Process and Product Development.

My academic appointments and teaching experience includes, Professor of the Practice in the Department of Chemical and Biomolecular Engineering at Vanderbilt University since 2011. At Vanderbilt, I co-teach three courses on Product and Process Design as well as two laboratory courses on Chemical Engineering Unit Operations. The design and laboratory courses include instruction on the entire design process, including instruction in Risk Analysis, Hazard and Operability Analysis (HAZOP) and Failure Mode and Effects Analysis (FMEA) with an emphasis on safe design. I am one of 2 design professors in the Chemical Engineering Department at Vanderbilt and I have recently established the Chemical Engineering Process Innovation Center at Vanderbilt that is a combined process and product laboratory facility along with a state-of-the-art design instruction facility where design, analysis, operation, and safety are all addressed throughout the chemical engineering students' junior and senior year of course instruction. I was an adjunct professor with the Department of Chemistry at the University of West Florida in 2006 where I taught one course in chemistry and two chemistry lab courses. In 2000, I developed and taught a Ph.D. course on process integration design at the Technical University of Denmark to a class of 20 doctoral engineering students from around the world. From 1990-1995, I was a Chemical Engineering Faculty Member at Auburn University, where I taught undergraduate courses in chemical engineering on Material Energy Balances and three chemical engineering laboratory courses.

I am author of numerous peer reviewed articles and book chapters regarding a variety of topics related to chemical engineering and materials science. I have taught courses on "*Nylon 6,6 Plastics and Polymers: Chemistry and Process Fundamentals," "Process Integration Technology for CLEANER Production: A Short Course on Energy Conservation and Waste Reduction Process Design, " "Process Integration Design Tools for Wastewater Reduction and Water Conservation in Chemical Process Industries," "Pollution Prevention through Process Integration," "An Introduction to Energy Integration Using Pinch Technology and Other Techniques," and "Optimal Design and Assessment of Waste-Management Processes.*" I have also co-authored two presentations on polypropylene transvaginal mesh: "Oxidation and Degradation of Polypropylene Transvaginal Mesh", at the IUGA 2015 Annual Conference in Nice France and "Failure Analysis of Transvaginal Mesh Products – a Biomaterials Perspective Using Materials Science Fundamentals at the American Institute of Chemical Engineers 2014 Annual Meeting in Atlanta.

Specifically, my expertise (skill, knowledge, training, education, and experience) are applied in the follow key areas that are *reliable* and *relevant* to this case:

Polymer Product Design, Manufacturing and Analysis Expertise

- Have for worked full-time for major polymer manufacturers, including General Electric and Monsanto Chemical Company.
- Have worked as a design consultant to the chemical and polymer industry since establishing my company in 2004 and clients have included DuPont, Westlake Chemical, Ascend Performance Materials, Sabic Innovative Plastics, Celanese, Cerex Advanced Fabrics, Solutia, and others.
- Have taught and am currently teaching polymer product safety case studies (both medical and non-medical products) and safety analysis techniques, including FMEA, at Vanderbilt University.
- Instruct and grade multiple groups' FMEA of chemical products and processes over the past 5 years at Vanderbilt University.

Risk Assessment Expertise, including Failure Mode and Effects Analysis

- Led multi-functional industrial teams (over 60 managers, engineers, chemists, etc.) to identify the root cause of failure of entire polymer product line and authored the overall technical report.
- Have taught and am currently teaching polymer product safety case studies and safety analysis techniques, including FMEA, at Vanderbilt University.
- Instruct and grade multiple groups' FMEA of chemical products and processes over the past 5 years at Vanderbilt University.

Polymer Product Failure Analysis Expertise:

- Have applied the use of *microscopic* (*e.g.* Scanning Electron Microscopy), *chemical analysis* (*e.g.* Fourier Transform Infrared Spectroscopy) and *thermal analysis* (*e.g.* Differential Scanning Calorimetry) techniques for the identification of the root cause of polymer product failure for hundreds of polymer products/designs and have provided over 200 technical reports on polymer failure analysis.
- Have significant prior experience analyzing polypropylene product failures for many applications; these include polypropylene fibers woven into straps used as a support harness in commercially available deer stand kits, its use in child car seat components, in automotive speaker grills, in plastic chairs, and many other polymer products where the use of plastic is required.

The expertise listed above is relevant to all polymer products, whether they are used in any application, including medical ones where it is used as an implantable device or for single-use products like syringes. My experience, education and training and a complete list of my published articles are more fully summarized in my Curriculum Vitae attached to this report at Exhibit A.

II. BACKGROUND

This report is an examination and assessment of the facts surrounding the Prolene-based pelvic mesh sold by Ethicon. In the course of my work, I analyzed and reviewed numerous depositions, exhibits, expert reports and discovery documents that were provided by counsel and at my request. These depositions, exhibits and discovery documents are identified in several indices at the end of this report.

The opinions expressed in this report are twofold. First, I present my opinions that were formed through using several industry standard polymer failure analyses, examining the use of Ethicon's polypropylene (PP) blend, Prolene, in the pelvic mesh application. Second, I present my opinions that were formed by utilizing several well-recognized product design methodologies, hazard control hierarchy and risk management principles and standards for Ethicon's Pelvic Organ Prolapse (POP) meshes utilized in the Prolift, Prolift +M, and Prosima devices.

Companies that manufacture all kinds of products, including Ethicon who manufactures medical devices, recognize both the need for and use of these kinds of analyses when designing products and performing risk management activities.

All of the opinions presented in this report focus only on the on the mesh utilized in Ethicon's Prolene-based pelvic mesh devices and they are presented to a reasonable degree of scientific certainty and within my fields of expertise. The Prolene-based mesh utilized in Ethicon's pelvic mesh devices is intended to be permanently implanted in a human body. As such, the mesh must be engineered to be as robust as possible for its intended purpose. In this report, I examine the fundamental flaws associated with the mesh's design.

III. SUMMARY OF POLYMER FAILURE OPINIONS

1) It has been well known for many decades that all forms of PP are highly susceptible to oxidation caused by the presence of a tertiary hydrogen on the polymer's chain. Oxidation and degradation of Ethicon's Prolene polypropylene is no exception. The addition of antioxidants to the Prolene blend only prolongs the time to oxidize and degrade the underlying PP, and it cannot be considered inert.

2) The failure analysis of medical polymers is included within the larger framework of the failure analysis of all polymers. The primary root cause of failure for PP used in medical products is oxidative degradation, leading to chain scission, embrittlement and ultimate failure.

3) Oxidative degradation and failure of PP components has been observed and published about since the polymer was first discovered. Knowledge of these failures should have been extended when considering the use of PP in any medical product, especially one intended to be implanted for the lifetime of a patient.

4) Ethicon scientists applied several polymer failure analysis methodologies on Prolene fibers that included numerous forms of standard polymer testing that are part of my expertise (scanning electron microscopy, chemical analysis and thermal analysis). Those scientists concluded numerous times, and beginning in the 1980's, that the root cause of cracked and degraded Prolene fibers was oxidative changes that were occurring *in vivo.* Additional polymer failure analyses were not performed to study any potential for injury that stemmed from using Prolene as a base for their pelvic mesh products, despite the knowledge that these *in vivo* changes were apparent.

5) External consultants hired by Ethicon reported that oxidative degradation was a likely cause of polymer failure in its mesh devices in 2011. This external review occurred over two decades after Ethicon's internal studies concluded that Prolene fibers were degrading inside the body.

6) The Prolene PP mesh used in Ethicon's pelvic mesh products is highly susceptible to oxidation and is, thus, prone to degradation after oxidation. Identification of the oxidative degradation defect in Prolene was both foreseeable and avoidable.

IV. POLYMER FAILURE OPINIONS

1.0 Polypropylene

1.1 Overview of Polypropylene

Polypropylene (PP) is a polymer that was introduced in the late 1950s. Polypropylene flakes and chips are generally manufactured from propylene gas, a component of natural gas. Polypropylene is generally formed by an addition reaction of the monomer propylene into polymers. After this polymerization occurs the fiber is typically melt-spun as filaments, where a single fiber strand is referred to as a monofilament.[1] The principle chemical structure of the polypropylene formed during this process is called "isotactic polypropylene" and it is shown below in Figure 1.

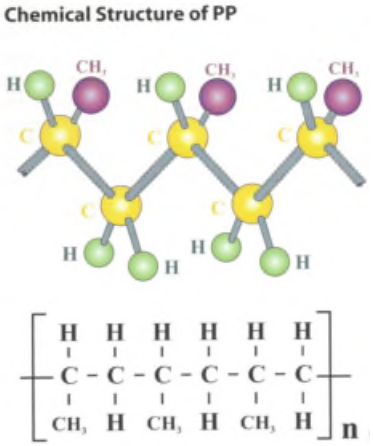

Figure 1. Polypropylene Chemical Structure[1]

1.2 Modifications to Polypropylene

1.2.1 General Modifications Made to Polypropylene

Different polypropylene grades within each classification are available, and can be chosen dependent on the application and processing method. It is possible to tailor grades of polypropylene with specific molecular properties and additives during manufacturing or during the extrusion part of the melt spinning process. Some examples of additives often incorporated into polypropylene include antioxidants, neutralizing agents, antistatic agents, slip agents and UV stabilizers.[1] For example, antistatic additives can be added to help polypropylene surfaces resist dust and dirt. It is in this sense that the intended use of the polymer becomes critical; the more a manufacturer knows about the intended environment, the more a manufacturer can do to prolong the properties that the polymer is desired to keep.

1.2.1 Ethicon Prolene Polypropylene

Ethicon sells permanently implantable polypropylene-based meshes intended to treat Stress Urinary Incontinence ("SUI") and Pelvic Organ Prolapse ("POP"). The Prolene-based mesh, used as a component in Ethicon's devices to treat POP, that was examined for this report was made from using Ethicon's Prolene resin.

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[1] Industrial Polymers, 2008, p. 74.
[2] Industrial Polymers, 2008, p. 74.

Prolene is Ethicon's proprietary blend of polypropylene that was originally developed for use as a suture material in the 1960's; it contains two antioxidants, Dilauralthiodipropionate (DLTDP) and Santonox R (which is a phenol)[2]. In addition, Prolene contains two lubricant additives and a colorant to enhance visibility.

1.3 Degradation of Polypropylene

All forms of PP are susceptible to oxidation (degradation) as shown in Table 1.[3] In fact, PP is reported to have the highest tendency for oxidative degradation when compared to other common commodity polymers as shown in Figure 2.[4]

Degradation of polypropylene occurs when the polymer is placed under certain kinds stress; these stresses can be environmental factors such as heat, light or mechanical influences, or these stresses can be more chemical in nature and take the form of acids, alkalis, or other oxidative species. The effect of these stresses can include the loss of tensile strength, changes to the appearance of the surface of the fibers, the polymer's color, and/or its shape. This degradation can be observed chemically by the appearance of hydroxyl and/or carbonyl bonds on the polypropylene that can be identified by the use of FTIR spectroscopy and/or X-ray photoelectron spectroscopy.[5]

[2] Eth.Mesh.02268619
[3] Applied Plastics Engineering Handbook, Processing and Materials, 2011, p. 44.
[4] Compositional and Failure Analysis of Polymers, 2000, p. 399.
[5] Compositional and Failure Analysis of Polymers, 2000, p. 398, 426.

Table 1: Polypropylene Oxidative Resistance[3]

3.5.2 Polypropylene

3.5.2.1 Physical properties of polypropylene (Table 3.10)

Table 3.10 Physical properties of polypropylene

	PP Homo	PP Copo	PP Impact
Optical	Transparent to opaque	Opaque	Opaque
T_g (°C)	−5	−20	−35
H_2O Absorption	0.01	0.01	0.01
Oxidation resistance	Low, oxides readily	Low, oxides readily	Low, oxides readily
UV resistance	With stabilization high	With stabilization high	With stabilization high

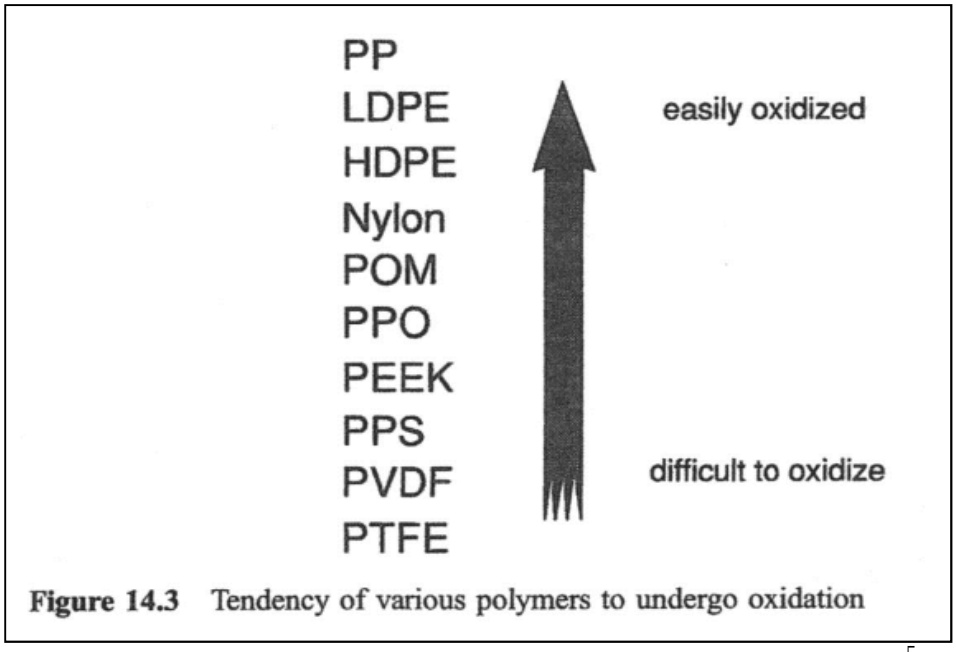


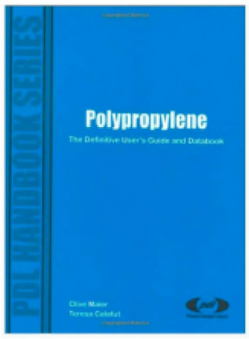
Figure 14.3 Tendency of various polymers to undergo oxidation

Figure 2. Tendency of Various Polymers to Undergo Oxidation[5]

1.3.1 Mechanism of Oxidative PP Degradation

The mechanisms of thermal and oxidative PP degradation have been investigated by the scientific extensively since the 1960s and were well known at the time that Ethicon was designing its Prolene-based pelvic mesh products. The oxidative behavior of PP described is independent of whether the polypropylene product is a medical device or a non-medical device.

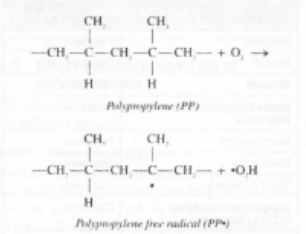
The initial oxidative attack on PP will occur on the hydrogen in the tertiary carbon position; this attack is also the rate-controlling step in the polymer's oxidative process. A detailed chemical explanation of polypropylene oxidative degradation is reported in literature and is summarized below in Figure 3, emphasizing the effect of the tertiary hydrogen on the susceptibility of polypropylene to chemical oxidation. The chemical mechanism for polypropylene oxidation and degradation leads to the formation of hydroperoxide bond (COOH) formations (an intermediate) and ultimately carbonyl (C=O) bond formations. Furthermore, polypropylene will exhibit autooxidation in the presence of a reactive oxygen species (ROS).



1.3.4 Oxidation

Polypropylene is highly susceptible to oxidation due to the presence of the tertiary hydrogen on the carbon atom bonded to the pendant methyl group. Polypropylene undergoes oxidation more readily than polyethylene, and oxidative chain scission, which reduces the molecular weight, occurs under normal processing conditions if the resin is not stabilized. [794, 795]

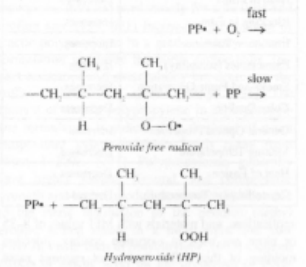
Polymer oxidation occurs through a free radical chain reaction. Mechanical stress, heat, or the presence of oxygen or metal catalyst residues results in homolytic cleavage of the carbon-hydrogen or carbon-carbon covalent bond in the polypropylene chain; each atom receives one electron from the two-electron covalent bond, producing two free radicals, each with an unpaired electron. An example of a chain initiation reaction in the presence of oxygen is given below:



Polypropylene (PP)

Polypropylene free radical (PP•)

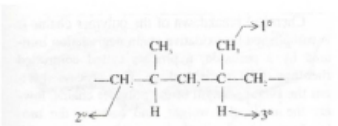
The chain reaction is propagated through the formation of a hydroperoxide, accompanied by the formation of another free radical:



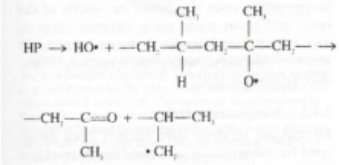
Peroxide free radical

Hydroperoxide (HP)

The oxidation rate is determined by the rate of the slow step in the chain propagation reactions. Due to the presence of the pendant methyl group, polypropylene contains tertiary (3°) hydrogen atoms, in which the carbon atom covalently bonded to the hydrogen is also bonded to three other carbon atoms. The free radical (PP•) formed from abstraction of a tertiary hydrogen is more stable than those formed from abstraction of a primary (1°; carbon atom attached to one other carbon) or secondary (2°; carbon atom attached to two other carbons) hydrogen, due to the tendency of carbon atoms along the chain to electronically donate electrons to the electron-deficient radical. The higher probability of reaction with the tertiary hydrogen considerably increases the susceptibility of polypropylene to oxidation. [768, 817]



In further reactions (chain branching reactions that increase the amount of free radicals), the hydroperoxide decomposes in the presence of heat or metal catalyst residues to form an alkoxy radical. Oxidative chain scission is believed to occur through disintegration of this alkoxy radical:



The decrease in molecular weight resulting from chain scission produces a gradual loss in mechanical properties. Crosslinking, which is common in polyethylene oxidation, producing an increase in viscosity, does not occur frequently in polypropylene due to preferential oxidative attack at the tertiary hydrogen, which leads to chain scission. Compounds such as carboxylic acids, lactones, aldehydes, and esters are also produced during oxidation reactions, resulting in chemical modifications such as yellowing. Chain reactions are terminated when two radicals combine to form an inactive species. [817, 818]

Figure 3. Oxidative Degradation of Polypropylene[6]

1.3.1 Effect of Oxidative PP Degradation

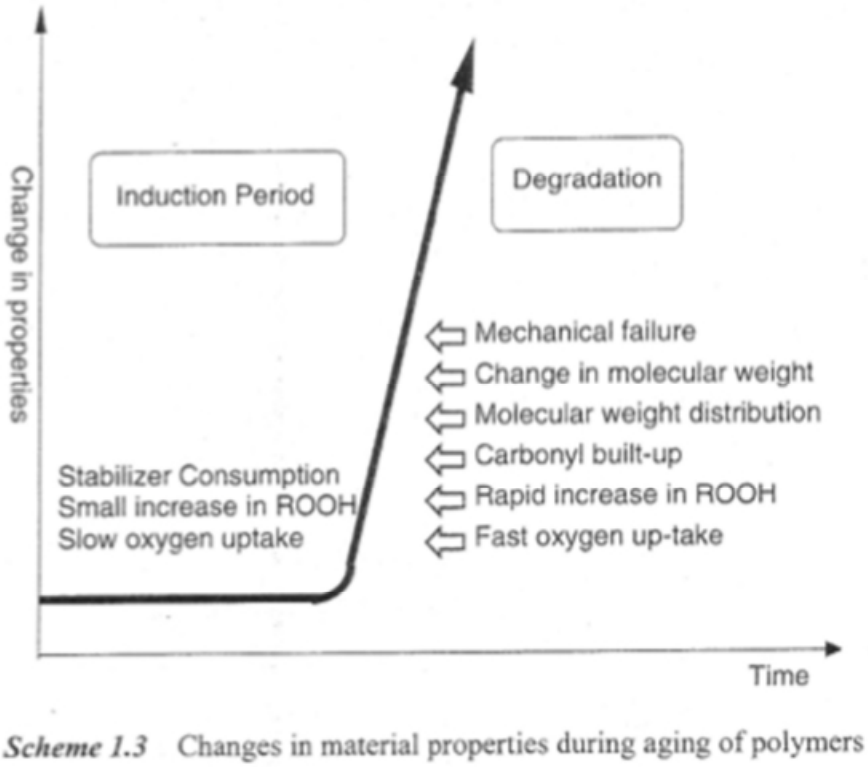
The basic mechanism of this degradation has been identified as follows:

Oxidation in PP amorphous phase => chain scission => rupture of tie chains => loss of ductility.[5]

Furthermore, this loss of ductility through oxidative degradation leads to embrittlement of the polymer, micro-crack formation, crack propagation and ultimate polypropylene polymer fracture and fragmentation.

The key features of oxidative degradation, in terms of ultimate elongation, the amount of molecular weight loss that is critical for embrittlement, and in terms of the increased carbonyl (CO) and carboxyl (OH) groups, are summarized in Figure 4.

[6] Polypropylene: The Definitive User's Guide and Databook, Maier and Calafut, 1999, p. 6-7.



Scheme 1.3 Changes in material properties during aging of polymers

Figure 4. Effect of Oxidative Degradation of Polymers[7]

In this Figure, and as discussed throughout this report, the *induction period* or *induction time* is defined as the period of time elapsed from when PP is first exposed to oxidation to the time when the polymer is transitioned to the ductile-brittle stage (also known as the embrittlement induction time, $t_{i,E}$), or the tangent on the concentration of carbonyl (or OH) groups formed on the surface of the polymer (spectrophotometric induction time, $t_{i,CO}$).

Fayolle has studied and reported this same effect on polypropylene in subcutaneous implants.[8]

Fayolle reported that at the induction time the reaction speeds up and becomes autocatalytic and with that, the concentration of carbonyl and OH groups on the surface of the PP increases dramatically. It is in this context then, that the addition of antioxidant stabilizers to polypropylene can extend the life of the resulting polymer by prolonging the time before the embrittlement stage from occurring.

Experiments on PP degradation have often been performed under accelerated conditions, such as elevated temperatures, in order to complete the experiments in a convenient period of time. However, it is important to note that the mechanism of oxidative degradation remains the same; that is, elevated temperature simply increases the rate of degradation according to the Arrhenius equation:

$$\text{rate} = A*e^{-EA/kT}$$

[7] Plastics Additives Handbook, Ch. 1 Antioxidants, Hans Zweifel, Ralph Maier and Michael Schiller, 2009, p. 6.
[8] Fayolle et al. Oxidation-induced embrittlement in polypropylene – a tensile testing study. Polym Degrad Stability 70:333-40, 2000

where A is the pre-exponential factor, E_a is the activation energy, k is the Boltzmann constant, and T is the temperature.

As previously stated, the some of the consequences of polypropylene oxidation are:

- Polymer chain scission
- Loss of polymer molecular weight
- Embrittlement
- Loss of polymer strength (cracking and ultimate mechanical failure)
- Hydroperoxide (COOH) bond increase
- Carbonyl (C=O) bond increase

1.3 Prolene Polypropylene

Ethicon uses the Prolene polypropylene for the mesh component of their transvaginal mesh products. The Prolene formulation has a polypropylene base resin purchased from Aristech and the polypropylene base resin portion comprises over 97% of the Prolene formulation. The remainder of the Prolene composition is comprised of small levels of two lubricants, two antioxidants and a colorant. Ethicon has been made aware of the specific risks inherent to using PP in an implantable medical device. One example of this is from the 2005 Material Safety Data Sheet (MSDS) that accompanied Ethicon's polypropylene; it stated:

> Section 10 (Stability and reactivity): Incompatibility: The following materials are incompatible with this product: *Strong oxidizers*, such as chlorine, *peroxides*, etc.[9] *(emphasis added)*

As previously stated, Ethicon has incorporated two antioxidants in their Prolene polypropylene, The specific antioxidants used in Prolene are Dilauralthiodipropionate (DLTDP) and Santonox R (which is a phenol)[10] First, the addition of these antioxidants in the Prolene formulation are evidence that this polypropylene is subject to oxidative degradation and must be protected from this effect. Second, the addition of these two anti-oxidants to the Prolene PP used in these pelvic meshes cannot render the material immune to oxidation. To the contrary, the correct proportion of these two anti-oxidants to maximize the time before PP embrittlement is shown in Figure 5 below.[11] Regardless of the fact that the ratios of these stabilizers are not in an optimal concentration in the Prolene material, even if it were, they would still eventually be depleted. When this occurs the PP is unprotected from oxidation. This is even more pronounced for a PP application that has a high surface area (per volume of the bulk), as it is with the mesh used in its products.

[9] ETH.MESH.05439518.
[10] Eth.Mesh.02268619
[11] Plastic Materials, John Brydson, 1999, p.261.

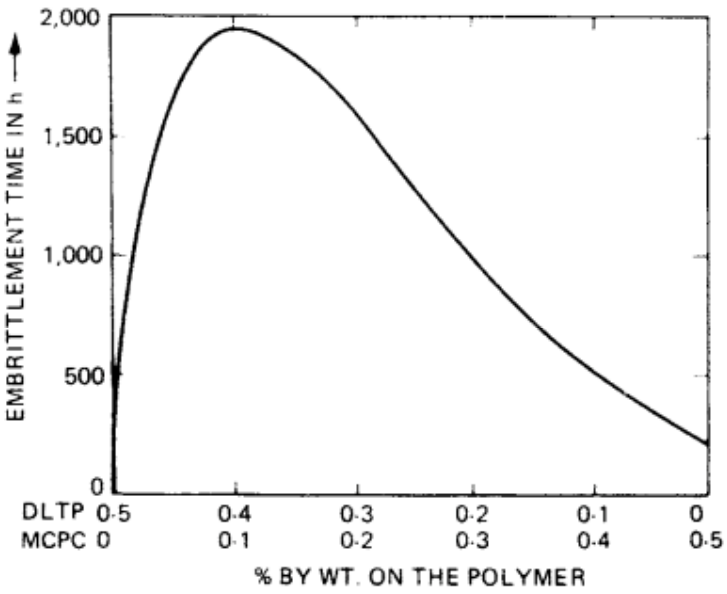


Figure 11.8. Synergistic effect of two antioxidants in polypropylene (DLTP=dilauryl thiodipropionate. MCPC–2,2′-methylenebis[6-(1-methylcyclohexyl-*p*-cresol)]. (After Leyland and Watts[8])

Figure 5. Time to Embrittlement for PP Stabilized with Phenol and/or DLTDP Antioxidants

Furthermore, Ethicon's decades-old findings of Prolene's vulnerability to oxidative changes inside the body, particularly in regards to the surface of explanted Prolene fibers that were studied internally, are supported by the chemical nature of the polymer blend, the available scientific literature[12] and an external consultant's report.[13]

In fact, Ethicon employees and consultants have reported that "decreased polypropylene content and larger pore size mesh exhibited reduction in inflammation and fibrosis"; clearly linking increased amounts of PP to increased negative effects on the body.[14] Indeed, the chemical properties of PP's reactivity, and the internal findings on explanted fibers, are not addressed in the device's design nor are they explained to the physicians who implant Prolene or those that are implanted with it. Instead, the company specifically represents that Prolene does not change and that it does not lose mechanical properties after implantation in the device's Instructions for Use ("IFU") and physician training materials.[15]

All forms of PP are susceptible to oxidation caused by the presence of a tertiary hydrogen on the polymer's chain.[16] Degradation of Prolene polypropylene is no exception. *Prolene PP is not inert.*

[12] Eth.Mesh.12831391, Eth.Mesh.12831407, Eth. Mesh. 12831405
[13] Eth.Mesh.07192412, Eth.Mesh.07192929
[14] Eth.Mesh. 04037600
[15] Eth.Mesh.00156909
[16] Industrial Polymers, 2008, p. 74.

Section 2.0 Polymer Product Failure Analysis:

2.1 Polymer Failure Analysis Applied to Medical Devices

Polymer failure analysis is a specific scientific discipline used by polymer scientists. Entire books have been written on the subject of polymer failure analysis and these sources contain numerous case studies covering a variety of polymer failures, including the failure of medical devices with one or more components made from a polymer(s).[17]

For example, Scheirs discusses the failure of a medical connector (Luer) that is used to attach intravenous lines and connect needles where the female Luer connector was found to be splitting, leaking, and cracking through polymer failure analysis.[18] In the Moalli text, the authors have addressed a shelf life prediction model for irradiated polypropylene medical devices, specifically to address catastrophic failure that have been reported during the PP shelf life period, specifically from the oxidation and embrittlement of the outer surface of the PP device. "A brittle layer is then formed and has the same effect as forming sharp notches on the sample, creating stress concentrations. Once the notch reaches a critical size, failure occurs".[19] Finally, Wright addressed the use of polypropylene for disposable medical products and clearly pointed out that PP "suffers from chain scission and severe post radiation oxidative degradation".[20]

Common themes found in these texts are:

- Failure analysis of *medical polymers* is included within the larger framework of failure analysis of any polymers. Polymer expertise is required to identify the root cause of failure.
- Numerous polypropylene based medical products have exhibited polymer failures.
- The primary root cause of failure of the polypropylene medical products cited is indeed oxidative degradation leading to chain scission, embrittlement and ultimate failure.

Specific steps should be followed when conducting polymer failure analysis. This protocol is cited in literature and one example showing the specific steps in this methodology is provided below in Figure 6.[21] The intent of polymer failure analysis is to identify the root cause of polymer failure (see section 2.4 in this report).

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[17] Plastics Failure: Analysis and Prevention, John Moalli, Editor, Plastics Design Library, 2001, 335pp.; Failure of Plastics and Rubber Products: Causes, Effects and Case Studies Involving Degradation, David Wright, 2001, Rapra Technology Limited, 371pp.; Compositional and Failure Analysis of Polymers: A Practical Approach, John Scheirs, 2000, John Wiley & Sons, 740pp.

[18] Compositional and Failure Analysis of Polymers: A Practical Approach, John Scheirs, 2000, p. 352.

[19] Plastics Failure: Analysis and Prevention, John Moalli, Editor, Shelf Life Failure Prediction for Irradiated Polypropylene Medical Devices, 2001, p. 201-207.

[20] Failure of Plastics and Rubber Products: Causes, Effects and Case Studies Involving Degradation, David Wright, 2001, p. 148.

[21] Characterization of Plastics in Failure Analysis, ASM Handbook, Vol. 11: Failure Analysis and Prevention, 2002, p. 437-459; Failure of Plastic Press Release Buttons in Automobile Seat Belts, 2005, R. F. Dunn, R. H. McSwain, T. Mills and B. Malone, *Engineering Failure Analysis*, 12, 81-98.

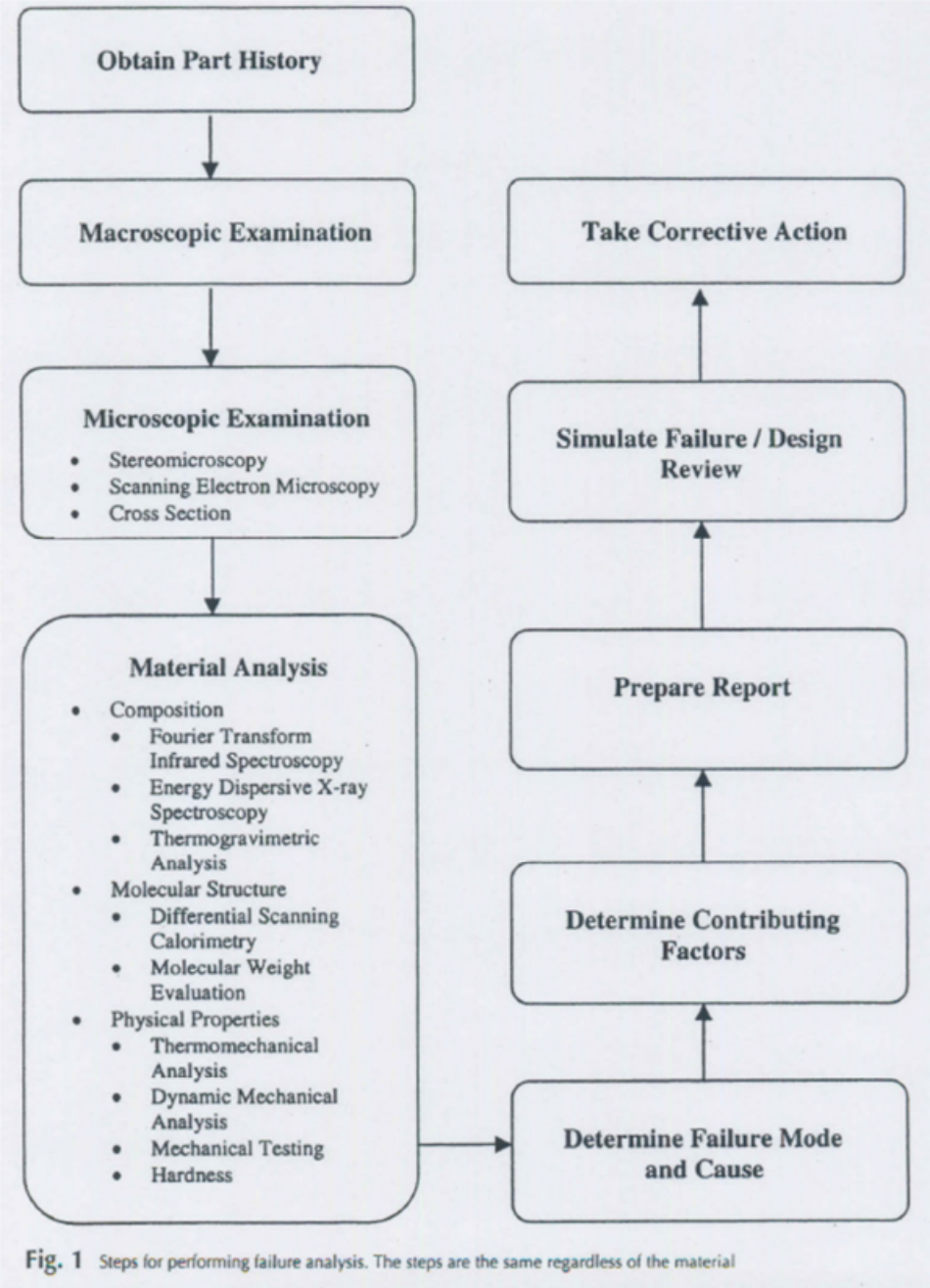

Figure 6. Polymer Failure Analysis Protocol

2.2 Microscopic Examination (Fractography) of Polymer Failures and Its Significance

Microscopic examination (stereo microscopy, scanning electron microscopy, etc.) of polymer failures is one of several critical steps in polymer failure analysis protocol. It is the third step shown previously in the failure analysis protocol provided in Figure 6. Again, this is specific field of polymer science called "fractography" and it focuses on microscopic features of polymer failures, generally at the fracture

surface. Entire books[22] are devoted to this subject and the American Society of Materials Handbook in Vol. 11 Failure Analysis and Prevention in their chapter on Fracture of Plastics has provided an overview article on this specific subject.[23] Microscopic examination, or fractography, is conducted on a failed polymer component regardless of what application the product was designed for. It does not matter if the polymer product was used in the body or outside the body; the microscopic examination technique and evaluation is the same.

Fractography is used to identify and analyze cracks. Specifically, polymers that crack and are under stress will exhibit crack propagation (crack growth), until ultimate polymer failure (fracture) occurs. Other polymer property changes, such as embrittlement, can occur prior to and contribute to ultimate failure. Microscopic examination of polymers is one of the techniques used to aid in the identification the root cause of polymer failure (see section 2.4).

2.3 Chemical and Thermal Analysis of Polymer Failures and Their Significance

Material analysis (chemical and thermal property analysis such as infrared spectroscopy, differential scanning calorimetry, etc.) of failed polymer components is one of several critical steps in polymer failure analysis protocol. It is the fourth step shown previously in the failure analysis protocol provided in Figure 6. This is specific field of polymer science called "fractography" and it focuses on features of polymer failures, generally at the fracture surface. Entire books[24] are devoted to this subject and the American Society of Materials Handbook in Vol. 11 Failure Analysis and Prevention in their chapter on Characterization of Plastics in Failure Analysis have provided an overview article of these techniques and how they can be used applied to polymer failure analysis.[25] Numerous chemical and thermal analysis techniques can be conducted, as required, on a failed polymer component regardless of what application the product was designed for. It does not matter if the polymer product was used in the body or outside the body; the material analysis is the same. Material analysis of polymers employs techniques that are used to aid in the identification the root cause of polymer failure (see section 2.4).

2.4 Identification of the Root Cause of Failure

Understanding how and why a polymer-based product failed is a crucial part of maintaining its safety and efficacy. This makes the need to understand the root cause of polymer failure paramount to maintaining a robust design.

> "The ultimate objective of a failure analysis is to ascertain the mode and cause of the failure, regardless of the material from which the part was fabricated…Reaching the objectives of the plastic failure analysis, namely, the determination of the mode and cause of failure, or expressed alternatively, evaluating how the part failed, requires a scientific approach and a broad knowledge of polymeric materials." "In many cases, a single cause cannot be identified, because multiple integrated factors may have contributed to the failure. All of the factors that affect the performance of a plastic component can be classified into one of four categories: material, design, processing, and service conditions.

[22] Polymer Microscopy, Second Edition, 1996, Linda C. Sawyer and David T. Grubb, 399pp.; An Atlas of Polymer Damage, Engel, Klingele, Ehrenstein, and Schaper, 1981, 256pp.; Fractography: Observing, Measuring and interpreting Fracture Surface Topography, Derek Hull, 1999, 366pp.
[23] Fracture of Plastics, ASM Handbook, Vol. 11: Failure analysis and Prevention, 2002, p. 650-661.
[24] Polymer Microscopy, Second Edition, 1996, Linda C. Sawyer and David T. Grubb, 399pp.; An Atlas of Polymer Damage, Engel, Klingele, Ehrenstein, and Schaper, 1981, 256pp.; Fractography: Observing, Measuring and interpreting Fracture Surface Topography, Derek Hull, 1999, 366pp.
[25] Fracture of Plastics, ASM Handbook, Vol. 11: Failure analysis and Prevention, 2002, p. 650-661.

> These factors do not act independently on the component but instead act in concert to determine the performance properties of the plastic component."[26]

This approach is standard for studying all types of polymer failures and it is represented in Figure 7 below.[27] It does not matter if the polymer product was used in the body or outside the body; these factors that affect the performance of a plastic component are the same.

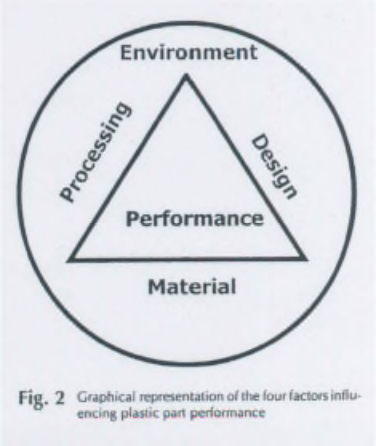

Figure 7. The Four Factors Influencing Plastic Part Performance

3.0 Ethicon's Internal Polymer Failure Analysis Studies

3.1 Ethicon Internal Studies Showed Oxidative Degradation of their Prolene Polypropylene

Ethicon observed evidence of PP oxidation and degradation in their own internal studies starting in the 1980's. At many points in time since first studying explanted material, Ethicon scientists have concluded that Prolene is vulnerable to oxidative changes inside the body—particularly in regards to the surface of the material.

- In 1982, Dr. Anthony Lunn reported in an internal Ethicon study that surface cracks were found on Prolene sutures explanted from vascular implants and ophthalmic implants.[28] Specifically, this report evaluated the surface crack depth on these implants. Surface cracks were found on sutures from both the vascular and ophthalmic implants. Dr. Lunn pointed out that "crack depth does not vary systematically with implantation time; it does vary significantly from point to pint along the fiber length".
- In 1983, Ms. Barbara Matlaga and Drs. W. D. Sheffield and A. W. Fetter published in an internal Ethicon study on Prolene (polypropylene) microcracks.[29] In this report, the authors noted that the "latest "human retrieval" specimens of Prolene suture showed surface microcracking. They further reported that they could show slides of these cracks "at the next Prolene Microcrack Committee" meeting. Furthermore, they concluded "surface cracking was noted on the Prolene sample from both explants. Why the cracking occurred or it this condition contributed to the loss of breaking strength (54%) could not be determined from this type of examination".
- In 1984, Dr. Peter Moy reported in an internal Ethicon study that microcracking of explanted

[26] Characterization of Plastics in Failure Analysis, ASM Handbook, Vol. 11: Failure Analysis and Prevention, 2002, p. 437.
[27] Id. P. 438.
[28] ETH.MESH.12831405, ETH.MESH.15406978
[29] ETH.MESH.15955438

Prolene sutures from vascular grafts was observed[30]. Dr. Moy points out "a great body of literature exists regarding oxidative degradation of polypropylene in general as well as selective studies on the photo- and thermal-oxidation of polypropylene monofilaments". He recommended further studies to examine "known oxidized Prolene samples".

- In 1985, a new Ethicon internal study was initiated where "twenty-four Beagle dogs were implanted in November 1985 with sutures made from four different polymers.[31] Each polymer suture type was implanted in six different locations (sites) in each dog. One of the suture polymer materials included in this study was Prolene PP. The study was referred to in Ethicon internal memos as the "*In Vivo* suture study".
- In 1987, Daniel F. Burkley, a Principal Scientist at Ethicon, examined Prolene sutures that were "carefully removed from human vascular graft explants".[32] Sutures were examined that had been in the body for 2 years and 8 years, respectively. Mr. Burkley conducted chemical analysis using infrared spectroscopy and also performed microscopic examination. Sutures that were in the body for eight years "were severely cracked specimens". Furthermore, Mr. Burkley stated that the surface of the sutures appears to be degraded polypropylene. He further concludes that he observes no protein in the FTIR (Fourier Transform Infrared Spectroscopy) spectra of the explanted sutures and that the FTIR spectra show that scraped surface material is consistent with polypropylene that has been "degraded in an oxidative fashion". He also observed changes in the DLTDP concentration, one of the antioxidants in Prolene, in the explanted Prolene sutures. He specifically reports that there is "no DLTDP observed in the surface scraped (cracked regions)" and that "the observed DLTDP decreases with implant time". Finally, Mr. Burkley also reported that the surface scrapings from the sutures that had been in the body for eight years (severely cracked) showed a melting point between 147-156^{o}C and that "this is the melting range previously observed for oxidatively degraded polypropylene."
- In 1987, a meeting was held to discuss the study previously cited above from that year.[33] Dr. Satya Garg published meeting minutes. In the meeting minutes, Dr. Garg reported:
  - Scanning electron microscopy showed that "explants with 7-9 years of residence time showed cracking"
  - Mr. Burkley examined the 2 and 8 year samples using IR spectroscopy. IR analysis showed "no proteinaceous material could be detected on either of the samples."
  - "The surface of the 8 year sample could be easily scraped off. The material scraped from the cracked surface regions of the 8 year sample showed IR bands indicative of oxidation. The same material exhibited a melting range of 147-156^{o}C which had been earlier assigned to oxidatively degraded polypropylene".
  - "Mr Burkley is planning to look at the remaining dry explants by IR. He will also try to see the relationship between the amount of stabilizers added to the polymer and degradation and cracking."
- In 1990, Elke Lindemann wrote an internal Ethicon five year report on the "*In Vivo* suture study". Specifically, five of the dogs were euthanized and the suture implants were removed for scanning electron microscopy examination. She concluded "out of seven Prolene explants, two revealed cracking". She further concluded that "after 5 years in vivo the PVDF suture was the only explanted material from five dogs that did not show any surface damage due to degradation."[34] This is consistent with the potential for oxidative degradation previously shown

[30] ETH.MESH.15958453
[31] ETH.MESH.11336474
[32] ETH.MESH.12831391
[33] ETH.MESH.12831407, ETH.MESH.15406846-15406999, ETH.MESH.15406978, ETH.MESH.15955438-15955473, ETH.MESH.15958336-15958469, ETH.MESH.15958470-15958477, ETH.MESH.15958336-15958469, ETH.MESH.
[34] ETH.MESH.11336474

in Figure 2 of this report.

- In 1990, Elke Lindemann, Eugene Muse, and Daniel Burkley, wrote an internal Ethicon seven year report on the "*In Vivo* suture study".[35] Specifically, four of the dogs were euthanized and the suture implants were removed for scanning electron microscopy examination. These Ethicon scientists concluded in this report that "the 7 year *in vivo* results generally substantiated the five year findings". The group further concluded that "degradation in Prolene is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking". Again, this is consistent with the potential for oxidative degradation previously shown in Figure 2 of this report.
- In 1999, Robert Rousseau, an Ethicon Staff Engineer in Suture Technologies, became the Project Leader for a "Prolene Mesh Improvement" project. Even at that time there was no consideration to change the material of construction from Prolene PP.[36]

3.2 Ethicon Failed to Investigate the Root Cause of Prolene Mesh Failures

Ethicon observed the oxidative degradation of their Prolene polypropylene as early as the 1980's. One example of this is from the 2005 Material Safety Data Sheet (MSDS) that accompanied Ethicon's polypropylene; it stated:

> Section 10 (Stability and reactivity): Incompatibility: The following materials are incompatible with this product: *Strong oxidizers*, such as chlorine, *peroxides*, etc.[37] *(emphasis added)*

As explained previously, as long as there is a source of oxygen, all polypropylene will be susceptible to oxidative changes, whether the polymer is implanted in a human being or if it is being stored at room temperature. The MSDS warning and the risks inherent to using a polypropylene-based mesh in the human body have not been addressed, which is to the detriment of all of those who have been implanted with this mesh.

This potential for oxidative degradation of Prolene polypropylene mesh was again reiterated to Ethicon in June 2011 through a technical review "Investigating Mesh Erosion in Pelvic Floor Repair."[38] This technical review was performed by PA Consulting Group at the request of Ethicon.

Furthermore, Ethicon's internal Prolene explant studies that employed industry-standard failure analyses and other evidence of oxidation should have led to the need for performing more testing on Prolene's reactivity before implanting their pelvic mesh into women.

At no time that I am aware has the potential failure mode of "oxidative degradation" of the Prolene-based mesh component of Ethicon's pelvic mesh products ever been considered and documented as a potential failure mode. As an illustration of the root cause of failure and the defective nature of these meshes, a summarized diagram is given below in Figure 8.

[35] ETH.MESH.09888187
[36] ETH.MESH.02608450
[37] ETH.MESH.05439518
[38] ETH.MESH.03750936-03750937

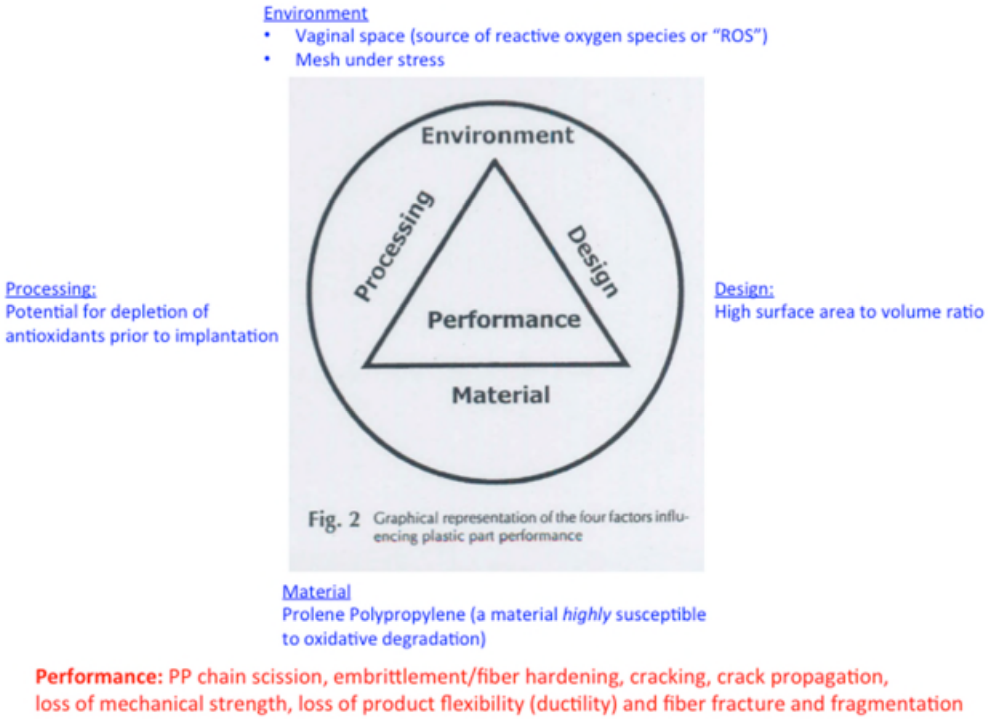

Figure 8. The Four Factors Influencing Plastic Part Performance Applied to Prolene-Based Mesh

3.3 Ethicon's Pelvic Mesh Products that Contain a Prolene-Based PP mesh are Defective

The Ethicon's pelvic mesh products are of a defective design since they contain Prolene-based meshes, a material that is highly susceptible to oxidation. All mesh components in every pelvic mesh device have this flaw. The potential for oxidation of Prolene polypropylene is common knowledge in the scientific community and the internal studies indicated that this was indeed occurring inside the body and that it resulted in polypropylene fiber embrittlement, cracking and a loss of fiber strength. Failure to account for this potential for polymer failure has resulted in the implantation of defective devices in patients. Identification of this defect in the mesh component of these products was both foreseeable and avoidable.

V. SUMMARY OF PRODUCT DESIGN OPINIONS

1) As part of its device design process, Ethicon performs risk management activities to ensure that any risks associated with its products are either designed out of the product or that those risks are mitigated as much as possible. The Standard Operating Procedure ("SOP") at Ethicon is to employ a Failure Modes and Effects Analysis to assess and mitigate these potential risks before any product is launched and while it is on the market. This SOP was not followed properly with respect to the Prosima, Prolift and Prolift+M devices.

2) Ethicon did not prior to product launch, or has not to date, considered oxidative degradation as a potential failure mode for their Prolene PP Gynemesh products. This is in direct contradiction of polymer literature on polypropylene oxidation, Ethicon's own internal studies, vendor MSDS sheets and external consultant studies.

3) Ethicon has not investigated the oxidative degradation of its Prolene polypropylene in their Prosima, Prolift and Prolift+M product's risk analysis. Had this potential failure mode been considered, it would have led to an evaluation of the risk of injury associated with this type of failure and would also have led to testing that assessed both the frequency and severity of it. Because of this, known risks of the Prosima, Prolift and Prolift+M products are not being mitigated to those who implant or are implanted with any of these products.

4) The risk analysis associated with oxidative degradation of the Prolene-based component of the Prosima, Prolift and Prolift+M devices was not adequately measured or assessed in terms of possible failure modes, frequency of occurrence, in terms of changes to mechanical properties, and in terms of the potential for harm caused prior to when this product was placed on the market; these deficiencies are lacking to this day.

5) The design of the Prosima, Prolift and Prolift+M devices was faulty in that Ethicon knew of a specific design defect before it ever launched these products: the high susceptibility of its Prolene PP to oxidatively degrade. Yet the design of the Prosima, Prolift and Prolift+M devices did not eliminate or mitigate the resulting risk of harm to the implantee.

6) The Prolene polypropylene mesh used in the Prosima, Prolift and Prolift+M devices is a defective design. Identification of the oxidative degradation design defect in these products was both foreseeable and avoidable.

VI. PROSIMA, PROLIFT AND PROLIFT+M PRODUCT DESIGN OPINIONS

1.0 Product Design

1.1 Phases of Product Design[39]

Different companies may have various descriptions for each phase of the product design and development process, but Robert Cooper's The Stage-Gate - Product-Development Process (SGPDP) captures the essence of this process and provides a roadmap to transform ideas into products that meet a consumer need. The typical phases may include:

(1) *Concept.* This phase includes idea generation, the development of a superior product concept, an identification of customer needs, market assessment, and the development of a risk assessment. The goal is to define the product and build the business model.

(2) *Feasibility.* This phase includes validating the superior product concept, building a business case, updating the market assessment, examining the health-safety concerns. Deliverables include product performance, a product prototype, and a case for the economic value of the product in the face of competition.

(3) *Design.* The objective during this phase is to fully develop the product and finalize the design. The deliverables include the product specification, a feasibility of the manufacturing, updating of market assessment, competitive analysis, and health and safety. The health and safety aspect are evaluated through an overall *Risk Management Plan.* A key component of the Risk Management Plan is an assessment of potential risks associated with product failures. This risk is addressed using a risk estimation tool such as Hazard/Risk analysis, *Failure Modes and Effects Analysis (FMEA),* or Fault Tree Analysis (FTA).

(4) *Verification.* This phase involves proving that the design meets all the requirements of the product. Testing at various levels of the design is conducted along a rigorous outline to assure the product meets the design requirements. All results are documented.

(5) *Manufacturing.* The goal is to develop a process to manufacture the product that meets the product specifications set in the design phase. A quality-assurance plan should be implemented and tested. The product is sampled and tested to assure it meets the design specifications.

(6) *Product Field Activity.* This phase involves monitoring and validating product performance and function in the field, assessing the product's success in achieving the intent of the design, analyzing field data, analyzing success and failure data, and documenting everything. This includes establishing and maintaining a functioning Quality System that obtains, tracks, and trends information regarding the product's function in the field (in this case after implantation). This information is then analyzed and fed back into the product's FMEA so that a decision can made regarding whether changes are warranted to the FMEA in design, warnings or if other remediating actions are required.

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[39] Product and Process Design Principles: Synthesis, Analysis and Evaluation, 3rd Edition, Seider, Seader, Lewin and Widalgo, 2009, 728pp.; Reliable Design of Medical Devices, Third Edition, Richard C. Fries, 2013, 471pp.

1.2 Risk Management Plan and Failure Mode and Effects Analysis

1.2.1 The Risk Management Plan

The Risk Management Plan outlines the specific risk assessment and risk minimization activities (if needed) associated with a product. The primary purpose of a Risk Management Plan is to proactively and systematically describe a set of specific safety monitoring and evaluation activities designed to identify, characterize, and minimize and/or prevent risks that may occur with the use of a particular product. After a product receives approval and is made available to patients, the Risk Management Plan continues to be updated as additional information becomes available that impacts the safety profile or benefit/risk balance of the product.

Specific instructions for risk management of medical devices can be found in ISO 14971 Medical Devices – Application of risk management to medical devices.[40] Ethicon uses the recommendations in ISO 14971 as guidance for its risk analysis for medical devices, including the use of the failure mode and effects analysis, [41] but the use of the FMEA is also mandated by internal SOP to provide a "methodology for evaluating and analyzing risks resulting from potential failure modes, with the objective of eliminating or minimizing these risks to an acceptable level with the current state of technology."[42]

Basic Elements of a Risk Management Plan:

• Identifies the important established or potential risks on the basis of non-clinical, clinical and post-marketing data

• Outlines how the risks will be monitored for further evaluation (e.g. by conducting additional studies, monitoring of existing databases)

• Specifies how the risk will be mitigated through a risk minimization plan. This plan describes a set of activities for minimizing the identified or potential risks of a product in order to optimize the benefit/risk balance.

Ethicon has stated that the risk analysis part of their Risk Management Plan to was intended for the:

- "identification of known or foreseeable hazards (such as oxidative degradation of Prolene polypropylene)
- identification of risks for hazardous situations" [43]

Oxidative degradation of the Prolene polypropylene was a foreseeable hazard based solely on the oxidative degradation properties of polypropylene that have been well documented outside the body for several decades.

Under this Risk Management Plan, oxidative degradation of Prolene polypropylene was a foreseeable hazard based solely on the oxidative degradation properties of polypropylene that have been well

[40] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.
[41] ETH.MESH.22007225
[42] ETH.MESH.03742864
[43] ETH.MESH.22007254

documented outside the body for several decades. In addition, and as discussed later and in more detail in this report, Ethicon performed several internal studies that concluded Prolene polypropylene oxidized and degraded while inside the body—many years before the Prosima device was first marketed. This means that the foreseeable and known hazards associated with using Prolene polypropylene in the Prosima mesh were apparent before it was ever used for its intended purpose—making the design of the Prosima defective according to standards set forth in Ethicon's Risk Management Plan.

1.2.2 Failure Mode and Effects Analysis

This type of analysis, Failure Modes and Effects Analysis ("FMEA"), began in the 1940s by the U.S. military and was further developed by the aerospace and automotive industries. NASA was one of the first organizations that used the FMEA on a regular basis. It was instituted in NASA after space shuttle challenger incident in 1986.

An FMEA is a step-by-step systematic safety analysis that is conducted by a team comprised of members having diverse and overlapping expertise for identifying all possible potential mode of failures in a design. "Failure modes" means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. "Effects analysis" refers to studying the consequences of those failures.

The FMEA also encompasses the identification of the potential cause of these failure modes, an estimate of their severity, their potential occurrence rate (frequency), as well as the potential for these failures to be detected. For an FMEA to work, all of these must be identified to ensure that the product's design is as robust as possible. Thereafter, the product's design process requires that the manufacturer attempt to mitigate the risks identified in the FMEA prior to marketing the product. This can occur through re-design, by way of instructions, by warning about the hazards, by training the product's users, or by any other means necessary.

As part of the FMEA process, and in order to design the product to be as robust as possible, it is crucial that manufacturers obtain inputs from many types of engineering designers, as well as those intended to use the product and other related professionals. Specifically, ISO 14971 provides the following guidelines concerning the qualification of the personnel involved in the FMEA generation:

> "It is most important to get people with the expertise necessary to perform risk management tasks. The risk management process requires people with expertise in areas such as:
>
> - how the medical device is constructed;
> - how the medical device works;
> - how the medical device is produced;
> - how the medical device is actually used;
> - how to apply the risk management process.
>
> In general, this will require several representatives from various functions or disciplines, each contributing their specialist knowledge. The balance and relation between individuals performing risk management tasks should be considered."[44]

[44] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.

As an example, a specialized *medical doctor* would have more expertise on:
- how the medical device works;
- how the medical device is actually used

and a specialized *chemical engineer/polymer engineer* would have more expertise on:
- how the medical device is constructed (e.g. polymer materials and properties);
- how the medical device is produced (manufacture of base PP polymer and Prolene fibers used in the Gynemesh);

and a specialized safety professional would have expertise on:

- how to apply the risk management process

As an example, Ethicon included the following personnel expertise as part of their design FMEA team for their Prolift device:[45]

- Gynecare R&D Project Leader
- Design Quality Engineer
- Packaging R&D Engineer
- Medical Director
- Design Quality Engineer
- Operation Integration Project Manager
- Medical Affairs Manager
- Equipment Engineer
- Process Engineer
- Process Engineer
- Quality Engineer

My expertise overlaps with Quality Engineers with expertise in FMEA's, an R&D Project Leader and Process Engineer. Several of Ethicon's design FMEA analysis did not have this depth of expertise on the safety analysis team.[46] It is unknown to me at this time if any of these individuals had sufficient polymer engineering background to understand the properties of polypropylene.

While there is often overlap between these medical, polymer and safety expertise, it is imperative that all of these skills are an integral part of the FMEA team that is conducting the risk analysis. The ISO 14971 standard clearly recognizes that the appropriate analysis of any potential failures requires a multi-discipline team and certainly not just medical doctors who have little, to no, polymer product training and polymer chemistry and property assessment.

The FMEA is not the end of a manufacturer's obligation to ensure that its products work as intended and are safe for their use. Instead, the FMEA is considered a living document that must be modified to take into account any additional risks or failure modes that are identified once a product has been placed on the market. To do this, product manufacturers create cyclical and redundant quality systems that monitor their products and feed information about any potential or additional risks that are encountered during their manufacture and use. After any information about a product's failure is gathered, it is then analyzed by the manufacturer who identifies the root cause of the product's failure. If and when an

[45] ETH.MESH.12288401, ETH.MESH.00876900
[46] Id.

additional risk is identified—that risk must be added to the original FMEA. This information regarding potential additional failure modes includes all information that can be learned from returned products (breakage, loss of components) as well as complaints of product failure and adverse events.

This evaluation and analysis process then repeats itself for every complaint or product failure for the entire life of the product. If properly employed, the FMEA is a powerful tool that will create and maintain a robust product design and it will help ensure that the product is on the market is safe and effective, that known and knowable risks will be identified, and warned about or mitigated.

It is crucial that the manufacturer obtain input from many types of professionals when developing the FMEA. A *Design FMEA* (D-FMEA)[47] is conducted during the design phase of product development and a *Process FMEA* (P-FMEA)[48] is conducted on the manufacturing process for a new product. An *Application FMEA*[49] is used to assess the specific steps associated with the use of a new product.

The Design FMEA is the critical safety assessment that is conducted by a manufacturer on a new product and this assessment evaluates each of the individual components that make up a product system. This includes such components as a trocar, a mesh(es), sheath covers, packaging, etc. when evaluating a transvaginal medical device used for SUI treatment. A manufacturer will systematically evaluate the safety of each component of the device along with any interactions between components, when conducting the Design FMEA. *The Design FMEA is the specific safety assessment that should include the potential failure mode of oxidative degradation for the mesh component of these mesh products.*

An FMEA requires the identification of all potential failure modes for a particular product. For each potential failure mode an estimate is made of its severity (S), of its occurrence rate (O) and its ability to be detected (D). Each of these rankings (S, O, & D) is typically on a scale of 1-10.

Examples of severity ranking criteria found in *Guidelines for Failure Mode & Effects Analysis for Medical Devices* and in ISO 14971 and these examples are provided in Tables 9 and 10, respectively.

[47] *Guidelines for Failure Mode & Effects Analysis for Medical Devices*, Chapter 11.
[48] *Id.* at Chapter 12
[49] *Id.* at Chapter 13

Table 9. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Severity Ranking – Example 1

Table 11-1: Suggested Severity Ranking for D-FMEA (1-10 qualitative scale)

Effect	Rank	Criteria
None	1	No effect.
Very Slight	2	Negligible effect on product performance. User not affected.
Slight	3	Slight effect on product performance. Non-vital faults will be noticed most of the time.
Minor	4	Minor effect on product performance. User slightly dissatisfied.
Moderate	5	Reduced performance with gradual performance degradation. User dissatisfied.
Severe	6	Product operable and safe but performance degraded. User dissatisfied.
High Severity	7	Product performance severely affected. User very dissatisfied.
Very High Severity	8	Product inoperable but safe. User very dissatisfied.
Extreme Severity	9	Product failure resulting in hazardous effects highly probable. Compliance with government regulations in jeopardy.
Maximum Severity	10	Product failure resulting in hazardous effects almost certain. Non-compliance with government regulations.

[50]

Table 10. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Severity Ranking – Example 2

Table D.3 — Example of five qualitative severity levels

Common terms	Possible description
Catastrophic	Results in patient death
Critical	Results in permanent impairment or life-threatening injury
Serious	Results in injury or impairment requiring professional medical intervention
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	Inconvenience or temporary discomfort

[51]

Likewise, examples of occurrence and detection ranking criteria found in *Guidelines for Failure Mode & Effects Analysis for Medical Devices* are shown in respectively in Tables 11 and 12 below.

[50] *Guidelines for Failure Mode & Effects Analysis for Medical Devices*, Chapter 11.
[51] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.

Table 11. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Occurrence Ranking

Table 11-2: Suggested Occurrence Ranking for D-FMEA (1-10 qualitative scale)

Occurrence	Rank	Criteria
Extremely Unlikely	1	Failure highly unlikely.
Remote Likelihood	2	Rare number of failures likely.
Very Low Likelihood	3	Very few failures likely.
Low Likelihood	4	Few failures likely.
Moderately Low Likelihood	5	Occasional failures likely.
Medium Likelihood	6	Medium number of failures likely.
Moderately High Likelihood	7	Moderately high number of failures likely.
High Likelihood	8	High number of failures likely.
Very High Likelihood	9	Very high number of failures likely.
Extremely Likely	10	Failure almost certain.

Table 12. ***Guidelines for Failure Mode & Effects Analysis for Medical Devices***

Detection Ranking

Table 11-3: Suggested Detection Ranking for D-FMEA (1-10 qualitative scale)

Detection	Rank	Criteria
Extremely Likely	1	Can be corrected prior to engineering prototype.
Very High Likelihood	2	Can be detected and corrected prior to engineering design release.
High Likelihood	3	Has high effectiveness.
Moderately High Likelihood	4	Has moderately high effectiveness.
Medium Likelihood	5	Has medium effectiveness.
Moderately Low Likelihood	6	Has moderately low effectiveness.
Low Likelihood	7	Has low effectiveness.
Very Low Likelihood	8	Has lowest effectiveness in each applicable category.
Remote Likelihood	9	Is unproven, unreliable or unknown.
Extremely Unlikely	10	No design technique available or known, and/or none is planned.

A Risk Priority Number (RPN) is assigned by multiplying the rankings for severity, occurrence and detection (RPN = Severity x Occurrence x Detection); therefore, an RPN is between 1-1000. The following are some key criteria when using an FMEA safety analysis:

• "An RPN greater than or equal to 100 indicates that there might be a high risk item."[52]

• "When the severity is very high (8-10), special attention must be given to ensure that the risk is addressed through existing design controls or corrective/preventive actions, regardless of the RPN."[53]

• "The severity can only be reduced through a change in the design. If such a design is attainable, the failure can possibly be eliminated."[54]

• "In the absence of any data on the probability of occurrence of harm, it is not possible to reach any risk estimate, and it is usually necessary to evaluate the risk on the basis of the nature of the harm alone. If it can be concluded that the hazard is of little practical consequence, the risk can be judged to be acceptable and no risk control measures are necessary. However, for significant hazards, that is, hazards which could inflict harm of high severity such as those noted above, no level of exposure can be identified that corresponds to a risk so low that there is no need to bother about it. In such cases, the risk estimate should be made on the basis of a reasonable worst-case estimate of probability."[55]

Although all three (severity, occurrence and detection) are important, special attention should be paid to severity. The FMEA also documents current knowledge and actions about the risks of failures, for use in continuous improvement. It is used during design to prevent failures and it is later used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

Risk control to design for inherent safety of a medical device can be achieved by: [56]

- eliminating a particular hazard,
- reducing the probability of occurrence of the harm

or

- reducing the severity of the harm.

The proper way for Ethicon to completely eliminate the hazard of oxidative degradation of the Prolene PP mesh component of its pelvic mesh products is to use a suitable polymer, other than Prolene-polypropylene, that is not highly susceptible to oxidative degradation.

1.2.3 Ethicon Safety Analysis and Design FMEA for Its Prosima, Prolift and Prolift+M POP Products Containing Prolene PP Mesh

Ethicon uses Prolene PP in the form of knitted monofilaments as part of the mesh component of its Prosima, Prolift and Prolift+M products. Ethicon has conducted Design FMEA's on their Prosima, Prolift and Prolift+M products. As part of Ethicon's safety analysis of these mesh products, they first developed a Qualitative and Quantitative Characteristics Worksheet to answer a number of critical

[52] *Guidelines for Failure Mode & Effects Analysis for Medical Devices*, p. 15-1.
[53] *Id* at p. 6-8.
[54] *Id* at p. 6-4.
[55] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.
[56] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.

questions about the product characteristics, including the mesh component. This worksheet serves to guide Ethicon employees and scientists in the creation of their design FMEA for each product. Some key questions from this worksheet that were not addressed correctly (answered as N/A or "not applicable") in order to consider oxidative degradation of the Prolene PP mesh are:[57]

- Are there any environmental factors that could influence safety/function of the device? N/A
- Are those components contacting biological materials compatible? N/A
- What is the effect of temperature on the system performance? N/A
- What is the effect of atmospheric gas concentration on system performance? N/A
- Is the device susceptible to environmental influences? N/A
- Do shipping temperatures affect device safety or functionality? N/A
- Does storage temperatures, humidity, or light affect device safety or functionality? N/A
- Does variation in the operating temperature, humidity, or light affect the device output or safety? N/A
- Is there any delayed or long-term user effect? N/A

All of these questions were answered incorrectly when properly considering the oxidative degradation properties of Prolene PP. All of these answers to their Qualitative and Quantitative Characteristics Worksheet as part of their safety analysis indicate that Ethicon did not and has not considered the oxidative degradation as a potential failure mode for these Gynemesh products. This is in direct contradiction of polymer literature on polypropylene oxidation, Ethicon's own internal studies, vendor MSDS sheets and external consultant studies.

Furthermore, Ethicon's design history files for the Prosima, Prolift and Prolift+M products provide a listing of potential hazards that is included as part Ethicon's safety analysis documents.[58] With the inclusion of this list in the design history files, Ethicon is asserting that this list was used to guide their safety analysis of these products. Key hazards included in this list are

- *Degradation*
- *Lack of adequate determination of end of device life*
- *Loss of mechanical integrity*
- *Likelihood of storage outside prescribed environmental conditions*

All of these suggested hazards for consideration should have triggered Ethicon's evaluation of oxidative degradation of their Prolene PP-based mesh used in their Prosima, Prolift and Prolift+M products.

[57] ETH.MESH.01962174-01962190, ETH.MESH.21989844-21990004, ETH.MESH.01154126-001154142
[58] ETH.MESH.21989844-21990004

Finally, and as a consequence of this inadequate safety analysis, Ethicon did not initially and has not to date considered oxidative degradation in any of its design FMEA's, which are their formal safety assessment document for the Prosima, Prolift and Prolift+M products. Again, the omission of oxidative degradation of Prolene PP fibers in the design FMEA's of these products is in direct contradiction of polymer literature on polypropylene oxidation, Ethicon's own internal studies, vendor MSDS sheets and external consultant studies. It is worth noting that all severities associated with failure of the mesh component as a result of any failure mode that was considered all result in high severities (8-10 on a 10 point scale).[59] Ethicon's description of their scale for severity rankings is included as Table 13 below.[60] Again, this indicates that Ethicon assesses that any failure of the mesh component of these devices results in severe harm to the implantee based on Ethicon's own assessment.

Table 13. ***Ethicon's Severity Ranking for Prolift+M dFMEA***

FMEA SEVERITY RANKING SCALE

NOTE: (F) denotes functional impact (A) denotes appearance impact

RANKING	DEGREE OF IMPACT
1	Improbable/Minor: Not perceptible or noticeable. (F) The consequences will not have any perceptible impact on the performance of the medical device. (A) The user will not notice the consequence.
2-3	Insignificant/Low, Negligible, Nuisance, Noticeable (F) Nuisance but likely negligible. (A) The user will probably notice only a minor negative impact on the medical device.
4-5	Moderately Significant/Dissatisfaction (A&F) The user will notice a negative impact as failure occurs, such as difficult to apply, difficult to use, discomfort, etc. (F) Partial loss of medical device operation or performs at a reduced level; possible gradual performance degradation.
6-7	Significant/High Annoyance (A&F) The failure causes greater annoyance to the user, such as creates pain. (F) Partial system function is lost, but the medical device can still be used without any safety concern.
8	Extreme/Very High: System function is lost (F) The medical device cannot be used, but failure does not create a safety, non-compliance or regulatory issue.
9	Almost catastrophic: Hazardous with warning (F) Medical device failure involves safety, non-compliance and/or regulatory issue. The user is forewarned that medical device failure is occurring.
10	Catastrophic: Hazardous without warning (F) Medical device failure involves safety, non-compliance and/or regulatory issue. The user is NOT forewarned that medical device failure is occurring.

ISO 14971 Medical Devices – Application of risk management to medical devices provides the necessary guidance for conducting the risk analysis of a new medical device. Furthermore, ISO 14971 clearly lists *chemical degradation* as one of its examples of initiating events and circumstances in ***Annex E: Examples of hazards, foreseeable sequences of events and hazardous situations***. This was not considered by Ethicon in their FMEA. Furthermore, ***Annex C: Questions that can be used to identify medical device characteristics that could impact on safety*** lists the following questions that should have further influenced Ethicon to fully assess chemical degradation of the Prolene polypropylene mesh used in their products.

[59] ETH.MESH.12288401-12288405
[60] ETH.MESH.02134781-02134783

C.2.2 Is the medical device intended to be implanted?
Factors that should be considered include *the location of implantation*, the characteristics of the patient population, age, weight, physical activity, *the effect of ageing on implant performance, the expected lifetime of* the implant, the reversibility of the implantation.

C.2.4 What *materials or components are utilized* in the medical device or are used with, or are *in contact with, the medical device*? Factors that should be considered include:
– *compatibility with relevant substances;*
– *compatibility with tissues or body fluids;*

C.2.21 Are there any *delayed or long-term use effects*?
Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, *long term material degradation.*

2.0 Ethicon Quality Systems and Risk Assessment

2.1 Ethicon Failed to Provide Feedback to Their FMEA

As part of the design process, design engineers and other members of a design team must use the FMEA and other tools available to them to assess all foreseeable issues with the launch and sale of the product. Using these tools ensures that the procedures in place and quality systems are robust enough to appropriately handle, investigate, and proactively address any issues that relate to their devices.

The evidence in this case demonstrates that the design documents did not contemplate several FMEA issues and that Ethicon did not have an adequate quality system in place to address complaint handling, investigation, and appropriate responses to patient complications and other issues as they relate to oxidative and other changes to the meshes found in these POP products.[61] As a result, Ethicon was not appropriately funneling information into the FMEA process, thus failing to meet basic requirements thereof, which places implantees at risk for failures that are not being assessed or mitigated by the company. This is a fundamental breakdown of how an FMEA risk analysis is conducted, and an FMEA created for medical devices is no different; [62] [63]failing to adequately assess and monitor potential failure modes of any engineered product is a flaw to ensuring the safety and efficacy of that device.

In addition, long-term storage of the raw material used to create these meshes prior to extruding the monofilament fibers poses substantial oxidation concerns. As a supplier of permanently implantable medical devices, by failing to control its resin and eventual processing of these meshes with respect to polypropylene's inherent tendency to oxidize, Ethicon has failed to account for the risk associated with its degradation during manufacturing and storage for all those who buy, implant or are implanted with these products.

All of these things and more are evidence that the Quality Systems at Ethicon are inadequate.

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[61] ETH.MESH. 00259473, ETH.MESH.00302411, ETH.MESH.00349122; ETH.MESH.05644163; ETH.MESH.02157879; ETH.MESH.02017169; ETH.MESH.03924557; ETH.MESH.00870466; ETH.MESH.07429428; ETH.MESH.02134849; ETH.MESH.04038032; ETH.MESH.21989844
[62] ISO 14971 Medical Devices – Application of risk management to medical devices, Second edition, 2007-10-01.
[63] ETH.MESH.03742864

2.2 Ethicon Internal Studies Showed Oxidative Degradation of their Prolene Polypropylene

Ethicon observed evidence of PP oxidation and degradation in their own internal studies starting in the 1980's. At many points in time since first studying explanted material, Ethicon scientists have concluded that Prolene is vulnerable to oxidative changes inside the body—particularly in regards to the surface of the material as previously discussed in the polymer failure analysis part of this report.

2.3 Ethicon Failed to Update the Prosima, Prolift and Prolift+M's Risk Assessment with Known Failure Modes.

Ethicon observed the oxidative degradation of their Prolene polypropylene as early as the 1980's. As explained previously, as long as there is a source of oxygen, all polypropylene will be susceptible to oxidative changes, whether the polymer is implanted in a human being or if it is being stored at room temperature. This potential for oxidative degradation of Prolene polypropylene mesh was again reiterated to Ethicon through a technical review "Investigating Mesh Erosion in Pelvic Floor Repair.[64] This technical review was performed by PA Consulting Group at the request of Ethicon.

Furthermore, Ethicon's internal Prolene explant studies and other evidence of oxidation should have made the company aware that it had additional obligations to perform more testing before implanting these POP products into women. At no time that I am aware has the potential failure mode of "oxidative degradation" of the Prolene component of the Prosima, Prolift and Prolift+M products ever been considered and documented in Ethicon's failure mode and effects analysis.

2.4 Ethicon's Prosima, Prolift and Prolift+M Devices are Defective Designs

The Prosima, Prolift and Prolift+M device are defective designs since they each contain Prolene polypropylene, a material that is highly susceptible to oxidation. All mesh components in every Prosima, Prolift and Prolift+M device have this design flaw. Ethicon was aware of the potential for oxidation degradation of Prolene polypropylene and their own internal studies and testing indicated that this degradation was indeed occurring. Ethicon was aware that this resulted in polypropylene fiber embrittlement and cracking and a loss of fiber strength. Furthermore, Ethicon did not initially, or at any later point, include the oxidation of the mesh component of their Prosima, Prolift and Prolift+M devices after implantation as part of their safety analysis (FMEA) of these products. Failure to do this has resulted in the implantation of defective devices in patients. Identification of this design defect in the mesh component of the Prosima, Prolift and Prolift+M products was both foreseeable and avoidable.

VII. FACTS OR DATA CONSIDERED IN FORMING OPINIONS

The opinions and the bases for those opinions are set forth above. In addition to my knowledge, skill training and experience as an engineer, the following depositions of Ethicon employees and the exhibits thereto were supplied to me: Cliff Volpe, Piet Hinoul, David Robinson, Sunny Rah, Aaron Kirkemo,

[64] ETH.MESH.03750936-03750937

Sean O'Bryan, Scott Ciarrocca, Vincenza Zaddem, Elizabeth Vailhe, Christophe Vailhe, Joerg Holste, Boris Batke, Daniel Burkley, Thomas Barbolt, Brigitte Hellhammer, Juergen Trzewik, Martin Weisberg, Axel Arnaud, Dan Smith, Prof Thomas Muehl, Dr. Bernd Klosterhalfen, Kevin Ong, Whenxin Zheng, Daniel Sexton, and Jeffrey Brent.

I have also considered the following material identified in Exhibit B.

In addition, the following reports were supplied to me: Dr. Howard Jordi, Dr. Scott Guelcher, Prof Thomas Muehl, Prof. Bernd Klosterhalfen, Thomas Barbolt, Dr. Wenxin Zheng, and B. Todd Heniford, M.D. The findings of these experts are consistent with my opinions.

VIII. EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF OPINIONS

All the Exhibits which I plan to use as summary of or in support of my opinions have not yet been determined, but they include, but are not limited to:

1) Exhibits extracted from the materials I have reviewed;

2) Excerpts from learned treatises and literature;

3) Materials listed above;

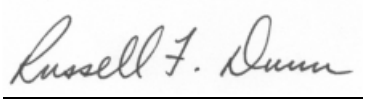
Any additional materials to be used will be timely disclosed.

IX. COMPENSATION AND TIME

A fee schedule for work on this case is attached as Exhibit C.

X. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FIVE YEARS

Please see Exhibit D.



Russell F. Dunn, Ph.D., P.E.
President
Polymer & Chemical Technologies, LLC

February 1, 2016